address tobacco-related disease and death, such as removal of the products from the market, were not believed to be feasible. It is now apparent, however, that FDA's authority to restrict the sale, distribution, and use of cigarettes and smokeless tobacco to people under the age of eighteen is an effective tool to reduce the adverse health consequences of tobacco use. Thus, asserting jurisdiction over cigarettes and smokeless tobacco now presents an opportunity to use the Agency's resources effectively for substantial public health gains.

1. New Information Shows that Cigarette and Smokeless Tobacco Use Begins Almost Exclusively in Childhood and Adolescence

Although it has long been known that some people begin tobacco use before adulthood, definitive analyses of data published in the 1990's have revealed that the vast majority of tobacco users begin their use while children or adolescents. Moreover, new evidence shows that children and adolescents are beginning to smoke at younger ages than ever before. The new analyses show that the average age when people first try smoking a cigarette is 14.5 years of age,[1182] 82% of adults who have ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age.[1183] Recent analyses also show that the mean average age when people become daily smokers is 17.7 years of age.[1184] These data have critical implications for public health interventions. As stated by the Surgeon General in 1994, "[n]early all first

[1182] *Id.* at 67.

[1183] *Id.* at 65.

[1184] *Id.* at 67.

use of tobacco occurs before high school graduation; this finding suggests that if adolescents can be kept tobacco-free, most will never start using tobacco."[1185]

Not only does tobacco use begin predominantly among children and adolescents, but recent evidence shows that more and more children and adolescents are using tobacco. Approximately three million American youths currently smoke and an additional one million adolescent males use smokeless tobacco.[1186] Despite a decline in smoking rates in most segments of the American adult population, the rates among children and adolescents have recently begun to rise.[1187] Tobacco use has been increasing among eighth and tenth graders in each of the last four years. In December 1995, 19% of eighth graders and 29% of tenth graders reported having smoked in the last 30 days, an increase of one-third since 1991.[1188] Tobacco use has also been increasing among high school seniors in each of the last three years. In December 1995, 33.5% of high school seniors reported having smoked in the last 30 days, an increase of one-fifth since 1992.[1189]

[1185] *Id.* at 5.

[1186] *Id.*

[1187] Centers for Disease Control and Prevention, Cigarette smoking among adults–United States, 1991, *Mortality and Morbidity Weekly Report*, 1993;42(12):230-233. *See* AR (Vol. 2 Ref. 17-1).

Johnston LD, O'Malley PM, Bachman JG, *National Survey Results on Drug Use from the Monitoring the Future Study 1975-1993, Vol. I: Secondary School Students*, NIH Pub. No. 94-3809 (Rockville, MD: National Institute on Drug Abuse, 1994), at 9, 19. *See* AR (Vol. 2 Ref. 17-1).

University of Michigan, News and Information Service, Smoking rates climb among American teenagers, who find smoking increasingly acceptable and seriously underestimate the risks (Jul. 20, 1995), at table 1. *See* AR (Vol. 3 Ref. 10-2).

[1188] Price J, Teen smoking, marijuana use increase sharply, study shows, *Washington Times* (Dec. 16, 1995), at A2. *See* AR (Vol. 711 Ref. 5).

[1189] *Id.*

There has been a similar increase in smokeless tobacco use by young people. Over the past 25 years, the market for smokeless tobacco has shifted dramatically from adults to young people. *See* Jurisdictional Analysis, 60 FR 41748. For example, use of moist snuff among males aged 18-19 increased from 0.5% in 1970 to 7.5% in 1991.[1190] Current use of smokeless tobacco by children and adolescents is high and begins early. School-based surveys in 1991 estimated that 19.2% of ninth- to twelfth-grade boys use smokeless tobacco.[1191] Among high school seniors who had ever tried smokeless tobacco, 73% did so by the ninth grade.[1192]

This increase in tobacco use by young people has severe public health consequences. Although they believe that they will not become addicted to tobacco, recent data establish that children and adolescents become addicted to nicotine in the same manner as adults. Among smokers aged 12-17, 70% already regret their decision to smoke and 66% say they want to quit.[1193] Those who are able to quit experience withdrawal symptoms and relapse rates similar to those reported in adults.[1194] As stated in a study of youthful smoking sponsored by the Canadian affiliate of Brown & Williamson:

[1190] Centers for Disease Control and Prevention, Office of Smoking and Health, unpublished data.

Informal communication between Office of Smoking and Health and Ann Witt, FDA.

[1191] Kann L, Warren W, Collins JL, Results from the national school-based 1991 youth risk behavior survey and progress toward achieving related youth objectives for the nation, *Public Health Reports*, 1993;108(Supp.1):47-54. *See* AR (Vol. 4 Ref. 24).

[1192] Surgeon General's Report, 1994, at 101. *See* AR (Vol. 133 Ref. 1596).

[1193] The George H. Gallup International Institute, *Teenage Attitudes and Behavior Concerning Tobacco-Report of the Findings* (Sep. 1992), at 54. *See* AR (Vol. 36 Ref. 381).

[1194] Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescent and young adult tobacco users-United States, 1993, *Morbidity and Mortality Weekly*, 1994;43(41):745-750. *See* AR (Vol. 2 Ref. 14-1). *See* AR (Vol. 2 Ref. 14-1).

> The desire to quit seems to come earlier now than before, even prior to the end of high school. In fact, it often seems to take hold as soon as the recent starter admits to himself that he is hooked on smoking. However, the desire to quit, and actually carrying it out, are two quite different things, as the would-be quitter soon learns.[1195]

A child or adolescent whose cigarette use continues into adulthood increases his or her risk of dying from cancer, cardiovascular disease, or lung disease.[1196] Indeed, approximately one out of every three young people who become regular smokers will die prematurely as a result.[1197] Moreover, the younger one begins to smoke, the more likely one is to become a heavy smoker and suffer from smoking-related diseases.[1198]

Smokeless tobacco use can cause oral cancer and the risk increases with increased exposure to smokeless tobacco use.[1199] One study of 117 high school students who were

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Surgeon General's Report, 1994, at 78. *See* AR (Vol. 133 Ref. 1596).

[1195] Kwechansky Marketing Research for Imperial Tobacco, Ltd., Project Plus/Minus (May 7, 1982), in Study Highlights. *See* AR (Vol. 21 Ref. 214).

[1196] McGinnis JM, Foege WH, Actual causes of death in the United States, *Journal of the American Medical Association*, 1993;270(18):2207-2212. *See* AR (Vol. 277 Ref. 3906).

[1197] Memorandum from Eriksen MP (CDC) to Lorraine C (FDA) (Aug. 7, 1995); CDC Fact Sheet based on Pierce JP, Fiore, MC, Novotny, TE, *et al.*, Trends in cigarette smoking in the United States: projections to the year 2000, *Journal of the American Medical Association* 1989;261:61-65 and Peto R, Lopez AD, Boreham J, et al., *Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from National Vital Statistics* (Oxford: Oxford University Press, 1994); Centers for Disease Control and Prevention, Office on Smoking and Health, unpublished data from the 1986 National Mortality Followback Survey. *See* AR (Vol. 711 Ref. 20).

[1198] Taioli E, Wyder EL, Effect of the age at which smoking begins on frequency of smoking in adulthood, *New England Journal of Medicine*, 1991;325(13):968-969. *See* AR (Vol. 101 Ref. 876).

Escobedo LG, Marcus SE, Holtzman D, Sports participation, age of smoking initiation, and the risk of smoking among U.S. high school students, *Journal of the American Medical Association*, 1993;269(11):1391-1395. *See* AR (Vol. 75 Ref. 149).

[1199] Department of Health and Human Services, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (1986) (Washington DC: DHHS), at 44. *See* AR (Vol. 128 Ref. 1591).

smokeless tobacco users revealed that nearly 50% had oral leukoplakia, a precancerous lesion that cannot be scraped off.[1200] Five percent of oral leukoplakias become malignant in 5 years.[1201] Tobacco use, which overwhelmingly begins in childhood, is ultimately responsible for over 400,000 deaths each year in the United States.[1202]

2. New Information Shows that Effective Restrictions on Access and Advertising to Children and Adolescents Can Decrease Tobacco Use by Children

Despite laws in every State making it illegal for minors to purchase tobacco, America's children have easy access to tobacco products and are subjected to pervasive advertising images that portray tobacco use in terms that are highly attractive to them. As described in the Proposed Rule, 60 FR 41321–41338 (Aug. 11, 1995) and in sections IV and VI.D.6 of the final rule, recent studies have shown that regulatory programs that are effective in restricting access to tobacco products by those under 18, and that restrict advertising of these products can substantially reduce illegal tobacco use by children and adolescents.

State laws prohibiting the purchase of tobacco by minors are rarely enforced[1203] and a significant percentage of underage smokers are able to obtain cigarettes through

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[1200] Greer RO, Poulson TC, Oral tissue alterations associated with the use of smokeless tobacco by teen-agers, *Oral Surgery, Oral Medicine, Oral Pathology,* 1983;56(3):275-284. *See* AR (Vol. 5 Ref. 95).

Surgeon General's Report, 1994, at 39. *See* AR (Vol. 133 Ref. 1596).

[1201] Surgeon General's Report, 1994, at 39. *See* AR (Vol. 133 Ref. 1596).

[1202] Centers for Disease Control and Prevention, Cigarette smoking–attributable mortality and years of potential life lost--United States, 1990, *Morbidity and Mortality Weekly Report,* 1993;42(33):645-649. *See* AR (Vol. 4 Ref 43).

[1203] Department of Health and Human Services, Office of the Inspector General, *Youth Access to Tobacco* (Washington DC: DHHS, Publication No. OEI-02-91-00880, Dec. 1992), at 5-8. *See* AR (Vol. 14 Ref. 19-1).

vending machines and over-the-counter sales.[1204] Studies show that most children and adolescents who use tobacco products purchase their own cigarettes and smokeless tobacco. The 1994 Surgeon General's Report, *Preventing Tobacco Use Among Young People*, examined 13 studies of over-the-counter sales and determined that approximately 67 percent of minors are able to purchase tobacco illegally. Moreover, successful cigarette purchases by children and adolescents from vending machines averaged 88%.[1205] In addition to over-the-counter and vending machine purchases, many children and adolescents receive cigarettes and smokeless tobacco through free samples distributed by tobacco manufacturers at shopping malls, zoos, baseball games, rock concerts, and through the mail.[1206] Even elementary school children receive free samples.[1207] Distributing free samples of "starter" brands to young people has been a cornerstone of the successful campaign to boost moist snuff sales by the largest smokeless tobacco

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Kusserow RP, Department of Health and Human Services, Office of the Inspector General, *Youth Access to Tobacco* (Washington DC: DHHS, Publication No. OEI-02-90-02310, May 1990), at 3-5. *See* AR (Vol. 4 Ref. 19-2).

[1204] Battelle for Centers for Disease Control and Prevention, Office of Smoking and Health, *Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors* (Apr. 1994), at 14, 18. *See* AR (Vol. 49 Ref. 529).

[1205] Surgeon General's Report, 1994, at 249. See AR (Vol. 133 Ref. 1596).

[1206] Davis RM, Jason LA, The distribution of free cigarette samples to minors, *American Journal of Preventive Medicine*, 1988;4(1):21-26. *See* AR (Vol. 7 Ref. 70-1).

Department of Health and Human Services, *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General* (Washington DC: DHHS, 1989), at 597. *See* AR (Vol. 130 Ref. 1593).

[1207] Davis RM, Jason LA, The distribution of free cigarette samples to minors, *American Journal of Preventive Medicine*, 1988;4(1):21-26. *See* AR (Vol. 7 Ref. 70-1).

manufacturer.[1208] *See also* section II.D., above. The distribution of free samples to minors occurs despite the industry's voluntary code against distributing tobacco products to minors.

Recent studies have shown that effective youth access restrictions can reduce tobacco use by young people. In one community, for example, a comprehensive and intense community intervention involving retailer licensing, regular compliance checks, and penalties for merchant violations significantly reduced illegal sales from 70% to less than 5% two years later. Further, rates of experimentation and regular smoking dropped by more than 50% among seventh- and eighth-graders.[1209] Both the Surgeon General of the United States and the Institute of Medicine have recently concluded that effective, enforced restrictions on minor's access to tobacco products are important tools to reduce use of tobacco by children and adolescents.[1210]

Pervasive advertising of tobacco products using imagery that is attractive to young people also influences children and adolescents to use tobacco products. Many studies have shown that young people are aware of, respond favorably to, and are influenced by cigarette advertising.[1211] Even very young children are aware of cigarette advertisements.

[1208] National Cancer Institute, *Strategies to Control Tobacco Use in the United States: A Blueprint for Public Health Action in 1990's* (Washington DC: NIH Publication No. 92-3316, Oct. 1991), at 236. *See* AR (Vol. 7 Ref. 72).

[1209] Jason LA, Ji PY, Aries MD, Active enforcement of cigarette control laws in the prevention of cigarette sales to minors, *Journal of the American Medical Association*, 1991;266(22):3159-3161. *See* AR (Vol. 6, Ref. 8).

[1210] Surgeon General's Report, 1994, at 254, 275. *See* AR (Vol. 133 Ref. 1596).

Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Washington DC: National Academy Press, 1994), at 199. *See* AR (Vol. 6 Ref. 11).

[1211] Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Washington DC: National Academy Press, 1994), at 123-124. *See* AR (Vol. 12 Ref. 149-1).

One study found that 30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking.[1212] Another study found that Joe Camel was more familiar to young children than Ronald McDonald, despite the fact that Ronald McDonald appears in television commercials, while cigarette commercials do not appear on the airwaves.[1213]

Moreover, recent studies show that campaigns that use imagery that is appealing to children and adolescents are successful in attracting young people to those brands. Before the Joe Camel cartoon character was introduced in 1986, Camel cigarettes had less than 3% of the youth market. By 1989, Camel's share of the youth market had risen to 8.1% and, by 1992, 13-16% of smokers under 18 were smoking Camel. During this same period, however, there was no significant increase in adult purchases of Camel cigarettes.[1214] These and other studies discussed in the Proposed Rule, 60 FR 41329–

Surgeon General's Report, 1994, at 188-192.

Tye JB, Warner K, Glantz SA, Tobacco advertising and consumption: evidence of a causal relationship, *Journal of Public Health Policy*, 1987;8:492-508. *See* AR (Vol. 48 Ref. 520).

Pierce JP, Evans N, Farkas AJ, Tobacco Use in California, *An Evaluation of the Tobacco Control Program, 1989-1993, A Report to the California Department of Health Services* (San Diego: University of California, 1994), at 85. *See* AR (Vol. 7 Ref. 93).

[1212] Fischer PM, MP Schwartz, Richards JW, Brand logo recognition by children aged 3 to 6 years, Mickey Mouse and Old Joe the Camel, *Journal of the American Medical Association*, 1991;266(22):3145-3148. *See* AR (Vol. 2 Ref. 24-2).

[1213] Mizerski R, *The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children, presented at Marketing & Public Policy Conference* (May 13-14, 1994). *See* AR (Vol. 13 Ref. 169).

[1214] Surgeon General's Report, 1994, at 70. *See* AR (Vol. 133 Ref. 1596).

U.S. Public Health Service and U.S. Department of Education, Teenage Attitudes and Practices Survey (1989), cited in Centers for Disease Control and Prevention, Changes in the cigarette brand preferences of adolescent smokers–United States, 1989-1993, *Morbidity and Mortality Weekly Report*, 1994;43(32):577-581. *See* AR (Vol. 13 Ref. 172).

The George H. Gallup International Institute, *Teenage Attitudes and Behavior Concerning Tobacco–Report of the Findings* (Sep. 1992), at 64. *See* AR (Vol. 36 Ref. 381).

41333, and in section VI.D. of the Final Rule provide compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products. Both the Surgeon General of the United States and the Institute of Medicine have concluded that unrestricted advertising of cigarettes and smokeless tobacco promotes consumption of tobacco by young people.[1215] Recent studies also show that government restrictions on tobacco promotion can reduce both tobacco consumption in the population as a whole, and initiation of tobacco use by young people.[1216]

3. New Information Indicates that Regulatory Interventions Can Reduce Tobacco-Related Illness If They Focus on Preventing Children from Becoming Addicted

Tobacco products have historically been legal and widely available in this country. It was only after millions of people became legally addicted to the nicotine in cigarettes and smokeless tobacco that health experts became fully aware of the extraordinary health risks involved in the consumption of these products. Consequently, tobacco use has

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Centers for Disease Control and Prevention, Changes in the cigarette brand preference of adolescent smokers, U.S. 1989-1993, *Morbidity and Mortality Weekly Report,* 1994;43(32):577-581. *See* AR (Vol. 2 Ref. 25-1).

[1215] Surgeon General's Report, 1994, at 10, 159-195. *See* AR (Vol. 133 Ref. 1596).

Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Washington DC: National Academy Press, 1994), at 131. *See* AR (Vol. 7 Ref. 96).

[1216] Toxic Substances Board, Wellington, New Zealand, *Health or Tobacco–an End to Tobacco Advertising and Promotion* (May 1989). *See* AR (Vol. 14 Ref. 178).

Smee C, *Effect of Tobacco Advertising on Tobacco Consumption-A Discussion Document Reviewing the Evidence* , 1-50 (London: Department of Health, Economics, and Operational Research Division, 1992) (draft). *See* AR (Vol. 14 Ref. 181).

Laugeson M, Meads C, Tobacco advertising restrictions, price, income and tobacco consumption in OECD countries, 1960-1986, *British Journal of Addiction* 1991;86:1343-1354. *See* AR (Vol. 15 Ref. 185).

become not only one of the most serious public health problems facing the United States today but one of the most difficult to solve.

Because of the grave health consequences of the use of tobacco products, it has been argued that FDA should exercise its jurisdiction to remove them from the market. As described in the Proposed Rule, 60 FR 41348–41349, and in section I.B of the final rule, however, a ban is not a feasible approach to a product to which 35 to 45 million Americans are addicted. Abrupt removal of these products from the market could cause widespread adverse reactions and, in any event, is unlikely to keep cigarettes and smokeless tobacco out of the hands of addicted users. Black markets are likely to develop to supply addicted users with these products, and these black market products could be even more dangerous than those currently on the market. Thus, removal of cigarettes and smokeless tobacco from the market would not be an effective use of FDA's regulatory resources. Before it was understood that nicotine addiction is a pediatric disease, moreover, there was an insufficient basis to conclude that other regulatory approaches available to FDA would constitute effective uses of the Agency's resources.

To effectively address the death and disease caused by tobacco products, addiction to cigarettes and smokeless tobacco must be eliminated or substantially reduced. The new evidence that nicotine addiction begins almost exclusively in childhood and adolescence demonstrates that this can be achieved by preventing children and adolescents from starting to use tobacco. Because the new evidence suggests that anyone who does not begin tobacco use in childhood or adolescence is unlikely ever to begin,[1217] effective

[1217] Surgeon General's Report, 1994, at 5, 58, 65-67. *See* AR (Vol. 133 Ref. 1596).